

## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 10 NOV 2005

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Applicant's or agent's file reference 03/11/EST	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/IT 03/00419	International filing date (day/month/year) 03.07.2003	Priority date (day/month/year) 03.07.2003	
International Patent Classification (IPC) or national classification and IPC A61K7/16			
Applicant BETAFARMA S.P.A. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 2 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  12.05.2004		Date of completion of this report  08.11.2005	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Sala-Jung, N  Telephone No. +49 89 2399-6050	



**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-4 as originally filed

**Claims, Numbers**

1-6 received on 29.07.2005 with letter of 28.07.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 2,3  
because:
    - ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
    - ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 2,3 are so unclear that no meaningful opinion could be formed (*specify*):  
**see separate sheet**
    - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
    - ☐ no international search report has been established for the said claims Nos.
    - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
      - the written form ☐ has not been furnished
      - ☐ does not comply with the standard
      - the computer readable form ☐ has not been furnished
      - ☐ does not comply with the standard
    - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
    - ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1,4-6
Inventive step (IS)	Yes: Claims	
	No: Claims	1,4-6
Industrial applicability (IA)	Yes: Claims	1,4-6
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Dependent claim 2 does not relate to a clearly defined subject-matter. It is the examiner's opinion that at least sorbitol, xylitol, sweetening agents, coloring substances and pH-adjusters are not antibacteric substances. Claim 3 is directly dependent from claim 2 and is therefore also not clear.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**V-1. Reference is made to the following documents:**

- D1: DATABASE CAPLUS [Online] XP002271164 retrieved from STN Database accession no. 1995:453547
- D2: WO 96/15770 A (WARNER LAMBERT CO) 30 May 1996 (1996-05-30)
- D3: US-A-5 294 431 (AFFLITTO JOHN ET AL) 15 March 1994 (1994-03-15)
- D4: EP-A-0 244 363 (WARNER LAMBERT CO) 4 November 1987 (1987-11-04)
- D5: US-A-5 401 496 (FITZIG SIMON ET AL) 28 March 1995 (1995-03-28)
- D6: WO 99/22703 A (LURIYA LEONID ; LURIDENT LTD (IL); LURIYA ELENA (IL)) 14 May 1999 (1999-05-14)
- D7: EP-A-0 528 457 (UNILEVER PLC ; UNILEVER NV (NL)) 24 February 1993 (1993-02-24)
- D8: US-A-5 416 075 (AU VAN ET AL) 16 May 1995 (1995-05-16)

**V-2. Novelty**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 4, 5, 6 is not new in the sense of Article 33(2) PCT.

The document D1 discloses a gargle which just prior to use comprises:  
an oil phase (polyethylene glycol, polyoxyethylene hydrogenated castor oil)  
containing antibacteric substances (1-menthol, eucalyptus oil) corresponding to a  
total of 6,7 g in 100ml gargle i.e. about 6,7%w/w,

and an aqueous phase containing antibacteric substances (cetylpyridinium chloride, ethyl alcohol) corresponding to the remaining about 92,3%w/w.

The subject-matter of claims 1, 4, 5, 6 is therefore anticipated by D1, although a film on the user teeth is not described in D1 (PCT Guidelines 5.21, 12.05).

The document D2 (ex.1) discloses an antimicrobial mouthwash containing an oil phase containing antibacteric substances (peppermint oil, methyl salicylate, thymol, menthol) and an aqueous phase containing antibacteric substances (cetylpyridinium chloride, ethyl alcohol).

The subject-matter of claims 1, 4, 5, 6 is not anticipated by D2 because the oil phase amounts to less than 5%w/w.

The document D3 (ex.1 C&D) discloses antimicrobial mouthrinses comprising an oil (flavoring oil) and a water-insoluble non cationic antibacterial agent (col.2, 1.34-40) (triclosan), water and ethanol as water soluble antibacteric substance. D3 (ex.2 C) also discloses a liquid dentifrice comprising a flavoring oil, triclosan, water and ethyl alcohol.

The subject-matter of claims 1, 4, 5, 6 is not anticipated by D3 because the oil phase amounts to less than 5%w/w.

The document D4 (ex.4) discloses an antimicrobial mouthrinse comprising an oil phase containing water-insoluble antibacteric substances (thymol, eucalyptol, methyl salicylate, menthol), water, and water soluble antibacteric substances (ethanol, chlorhexidine digluconate).

The subject-matter of claims 1, 4, 5, 6 is not anticipated by D4 because the oil phase amounts to less than 5%w/w.

The document D5 (ex.2,6) discloses an antimicrobial mouthwash containing an oil phase (ESTOL 3604, refined cod liver oil) containing an antibacteric substance (menthol) and an aqueous phase containing a water soluble antibacteric substance (hexadecyltrimethylammonium chloride or chlorhexidine digluconate) and an oil in water emulsifier (emulgin sml-20, polyoxyethylene-20-sorbitan monolaureate). The aqueous phase amounts respectively to 68,6 and 68,5 %w/w, the remaining being the oil phase. Eventhough the formation of a protective oil film is not explicitly

disclosed, it is deduced from all matching technical characteristics (chemical composition) that this disclosure is very relevant. Therefore, in accordance with PCT Guidelines 5.21 and 12.05, the subject-matter of claims 1, 4, 5, 6 is considered as anticipated by D5.

The document D6 (ex.5,6) discloses antimicrobial mouthwash formulations containing: ex.5: an oil phase containing an antibacteric substance (menthol) and an aqueous phase containing water soluble antibacteric substances (chlorhexidine diacetate, ethanol), ex.6: an oil phase containing antibacteric substances (triclosan, menthol) and an aqueous phase containing a water soluble antibacteric substance (ethanol). The lipid carrier has a high adhesiveness to the oral tissues (p.3, l.7- p.4, l.11).

The subject-matter of claims 1, 4, 5, 6 is not anticipated by D6 because the oil phase amounts to less than 5%w/w.

**V-3. Inventive step**

As none of claims 1, 4, 5, 6 is new, no inventive step can be discussed. It is nevertheless noted that documents D5 to D8 appear to be relevant.

D

## CLAIMS

1. A mouthwash antibacteric composition for sanitizing the buccal cavity, said antibacteric composition comprising an oil phase and an aqueous phase, characterized in that said composition further comprises, dissolved in said oil phase, antiseptic substances exclusively soluble in said oil phase, and, dissolved in said aqueous phase, water soluble antibacteric substances, in that said aqueous phase varies from about 60% w/w to about 95% w/w, that said oil phase varies from about 5% w/w to about 40% w/w, thereby said composition forms on a user teeth an oil film resisting against water rinsings.

2. A composition, according to claim 1, characterized in that said water soluble antibacteric substances comprise moistening agents, alcohols, fluorinated salts, sweetening substances, coloring substances, pH adjusters and so on.

3. A composition, according to claim 2, characterized in that said moistening substances are selected from glycerol, sorbitol, xylitol, glycoles, said alcohols being selected from ethyl alcohol and propyl alcohol and said sweetening substances being selected from saccharine and aspartames.

4. A composition, according to claim 1, characterized in that said oil phase comprises vegetable oils, mineral oils, aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons.

5. A composition, according to claim 1, characterized in that said oil phase comprises



aromatizing oils.

6. A composition, according to one or more of the preceding claims, characterized in that said composition further comprises an emulsifying system of an oil in water (O/W) type, adapted to form stable emulsions.